PEPFAR
U.S. President's Emergency Plan for AIDS Relief

Global HIV/AIDS: *International Laboratories*

CDC is establishing and strengthening international laboratories for rapid, effective disease response

A strong national public health laboratory system is essential for responding effectively to HIV and other diseases, and is crucial to rapidly detect and control emerging global public health threats. As a key partner agency for the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), CDC works with countries to build high quality laboratory systems and services that are critical for HIV prevention, care and treatment, as well as for other diseases. CDC also works to leverage PEPFAR resources including laboratories by linking them to other mainstream healthcare services. This integrated healthcare approach strengthens a country's entire healthcare system.

Scientific and technical expertise to establish high quality international laboratory systems and services

CDC works with Ministries of Health to ensure that all scientific and technical aspects of laboratory procurement, standardization, quality control, and quality assurance are established by:

- **Building high quality laboratory systems and services** for diagnosis in support of HIV care and treatment, prevention, and HIV/tuberculosis (TB) co-infection. CDC provides support on quality control and quality assurance of laboratories and testing activities. Examples include:
  - CDC, in collaboration with the World Health Organization (WHO), developed an HIV drug resistance detection tool to test dried blood spots that helped cut the cost of HIV drug resistance testing by almost 50%.
  - Working with Ministries of Health and other in-country partners, CDC implemented and expanded Early Infant Diagnosis (EID) services in more than 25 countries to give HIV-infected infants early access to appropriate care and treatment.
  - CDC developed training and quality assurance tools for HIV rapid testing that are widely implemented at thousands of testing sites in PEPFAR-supported countries.
- **Providing technical expertise for laboratory** accreditation to expand and standardize the quality of laboratories for a sustainable system. Examples include:
  - CDC, in collaboration with WHO and African host governments, conceived and launched the first African laboratory accreditation program in 2009 to ensure that high quality laboratory networks are established and sustained. CDC also played a key role in developing a training program to support laboratory improvement and accelerate accreditation preparation.
  - CDC was instrumental in establishing the first African Society for Laboratory Medicine, a key organization for administering the laboratory accreditation program and strengthening capacity building for country ownership.
  - With support from CDC, national laboratories in Ethiopia and Kenya were accredited by WHO ResNet to perform quality-assured testing to support HIV drug-resistance surveillance.
- **Providing technical expertise on evaluation and implementation of equipment and assays** for appropriate use and placement in PEPFAR-supported countries.
  - CDC evaluated the performance of a new point-of-care CD4 assay used to assess immune status of HIV-positive patients to determine antiretroviral drug eligibility.

Critical leadership for transitioning sustainable laboratory systems and services to local country ownership

CDC collaborates with Ministries of Health to build their capacity to establish and maintain national laboratory systems and services by:

Public Health Impact: International Laboratories

Quality laboratory systems are essential for detecting and responding effectively to HIV and other diseases. CDC, through PEPFAR, has helped support the development of the following*:

- More than **1,900** full and integrated, non-disease specific, clinical laboratories
- More than **16,500** HIV testing sites throughout the world
- Diagnostic assistance and training to in-country laboratories that collectively tested **11 million** pregnant women for HIV, leading to the prevention of mother-to-child transmission and allowing **230,000** infants to be born HIV-free (Fiscal year 2012)
- Over **280** laboratories in **22** countries working towards laboratory accreditation
- National strategic plans for laboratories in **18** countries for the transition of laboratory systems and services to country ownership
- **481** laboratorians trained from **23** countries through the African Center for Integrated Laboratory Training

*Fiscal year 2011 unless otherwise indicated

All CDC global HIV/AIDS activities are implemented by the Division of Global HIV/AIDS, CDC Center for Global Health, as part of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).

- **Providing technical expertise to develop national strategic plans for laboratories** that help countries respond effectively to HIV and other diseases, and support the transition of laboratory systems and services to country ownership.
- **Providing on-site training and mentoring to develop a qualified local workforce** capable of managing efficient laboratories that support quality assurance systems and timely, reliable testing.
  - CDC collaborated with the South Africa Ministry of Health to establish the African Centre for Integrated Laboratory Training in Johannesburg.
  - Through the African Society for Laboratory Medicine, CDC is working to develop in-country capacity to conduct laboratory-related research to facilitate evidence-based decision-making.
  - CDC, in collaboration with WHO, has developed a standardized laboratory training package for HIV drug resistance testing.

Notable Accomplishments: International Laboratories

Accreditation Program for Laboratory Quality Improvement

CDC, in collaboration with the WHO Regional Office for Africa and 12 African governments, developed and implemented the first African laboratory accreditation program to provide better training and expand testing capacity. To support countries in achieving accreditation, CDC was instrumental in developing the Strengthening Laboratory Management towards Accreditation program. CDC also partnered with WHO to develop a corresponding checklist to monitor and improve the quality of laboratory results related to HIV/AIDS and other diseases, including for rapid identification of emerging health threats.

African Society of Laboratory Medicine

CDC was instrumental in establishing the first-of-its-kind African Society of Laboratory Medicine (ASLM) in collaboration with WHO, Ministries of Health, the African Union, and other partners. ASLM serves as a professional body to guide and strengthen laboratory network development in Africa. It is composed of African Ministries of Health and sub-Sahara African laboratorians as well as other local, national, and international leaders, and partners, who will serve as the accrediting body for the laboratory accreditation program.

Regional Center of Excellence for Laboratory Training

CDC helped establish the African Centre for Integrated Laboratory Training in Johannesburg, South Africa, which serves as a regional training center to increase the pool of laboratory technicians and health care workers trained in HIV and tuberculosis diagnostics throughout Africa. Hundreds of laboratory scientists and managers from over 20 countries in sub-Saharan Africa, Asia, and the Caribbean have participated in this intensive hands-on training. Currently, CDC is working to establish regional training centers for West and East Africa.

National Strategic Plans for Laboratories

To further promote country ownership while building capacity, CDC has partnered with Ministries of Health to support the development of national strategic plans for laboratories. Using CDC's integrated, non disease-specific approach to strengthen laboratory systems, these plans support all health sectors, build efficiencies, and enable countries to respond effectively to HIV and other diseases, including emerging public health threats. For the first time, 18 African Ministries of Health now have fully integrated and comprehensive laboratory plans.

Ensuring the Quality of HIV Testing

CDC has established a standardized program to validate new HIV rapid tests for potential use in PEPFAR-supported countries. The program is unique in that it uses a large panel of well characterized specimens from all over the world to assess test performance. In the last 5 years, more than 40 new kits have been evaluated; one-third were rejected because they failed to meet the performance standards. CDC also developed simple and practical quality assurance tools that are widely used in countries to monitor and ensure quality of HIV rapid testing.

Early Infant Diagnosis for Early Access to Care and Treatment

Studies show that, left unidentified and untreated, 50-60% of HIV-infected infants die by age two. CDC led the development of the Early Infant Diagnosis (EID) testing procedure that gives HIV-infected infants early access to diagnosis and appropriate care and treatment. With a simple prick of an infant's heel, toe, or finger, blood is placed onto a card to dry, creating samples that remain stable for relatively long periods without refrigeration, making them simple to transport for testing. CDC has worked with Ministries of Health and other in-country partners to implement and expand EID services in more than 25 countries. To ensure quality testing, CDC also developed and administered an EID testing program to more than 100 laboratories in 40 countries.

HIV Drug Resistance Testing and Training

In Asia, Central America, and Africa, CDC provided technical support and training to 18 countries for HIV drug-resistance testing. CDC developed a low cost, broadly sensitive genotyping assay that cut the reagent cost for HIV drug-resistance testing by 70% and was implemented in the National Drug Resistance Laboratories in Ethiopia, Kenya, South Africa, and Tanzania. The assay, which uses dried blood spot technology, made HIV drug-resistance testing in remote areas a reality.

Viral load testing for monitoring patients on highly active antiretroviral therapy (HAART)

As more persons are identified as HIV-positive and receive antiretroviral treatment, there are pressing needs to monitor the viral load. Typically, viral-load testing requires human plasma but CDC is leading the push towards using dried blood spots (DBS) in resource-limited settings. CDC developed training curricula for viral-load testing on two major molecular platforms and is offering training on DBS collection and testing. To ensure quality viral load testing, CDC also developed and administered a novel dried tube specimen viral-load proficiency testing program to more than 100 laboratories in 40 countries.